K110614

NOV 2 1 2011

510(K) Summary

1. Identification of the device
   Proprietary-Trade Name: PAD (Personal Alcohol Detector)
   Classification Name: DJZ, 21 CFR section 862.3050, Device, breath trapping, alcohol
   Common/Usual Name: Breath-alcohol test system

2. Equivalent legally marketed devices
   Model:AL2500
   K Number: K053332

3. Indication for use (Intended use):
   The PAD Breath Alcohol Tester is a screening device for the rapid detection of alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcoholic intoxication.

   Intended use is the same as the predicate device

4. Description of the Device:
   The PAD is a self-contained unit with 3 digit LCD display, and power button. The 3 digit LCD display window displays the alcohol concentration in increment of 0.01%. The display is also capable of displaying L-b, S-E, t-F, L-t, n-C, HI and these states low battery, sensor error, test fail, low temperature, need calibration ,high concentration, respectively. The unit is powered by two AAA batteries.

5. Safety and Effectiveness, comparison to predicate device
   The results of bench and user testing indicate that the new device is as safe and effective as the predicate device. A clinical trial was performed to establish that the user could read and understand the instructions provided, and properly use the device, as well as perform comparably to an evidentiary type of breath alcohol tester.

6. Substantial Equivalence Chart

Similarities

Item	Device	Predicate
Method	Breath alcohol concentration to BAC	Breath alcohol concentration to BAC
Measurement Accuracy	±0.01at 0.10%BAC	±0.01at 0.10%BAC
Sensor Type	Semiconductor oxide sensor	Semiconductor oxide sensor
Certification	Not currently DOT approved	DOT/ NHTSA

Warm-up time	About 20 seconds	About 20 seconds
Practitioner use	Over-The-Counter	Over-The-Counter
Construction	Circuit board housed in plastic casing	Circuit board housed in plastic casing
Construction	No mouthpiece	No mouthpiece
Display	3-digit LCD	3-digit LCD

Differences

Item	Device	Predicate
Power Source	2(1.5V each) AAA alkaline batteries	2(1.5V each) AA alkaline batteries
Testing Capacity	Approx. 800(on 2 batteries)	Approx. 200-300(on 2 batteries)
Measurement Range	0.00% to 0.20%	0.00% to 0.40%
Dimensions	90x30x17mm	5"×3¼"×1"
Weight	45g	171g

7. Conclusion

After analyzing bench test, a risk analysis, EMC and user testing data, it is the conclusion of SEJU Engineering Col, Ltd. that the PAD is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device. The clinical trial performed showed that the over the counter purchaser of this device could read and understand the instructions, could properly use the device, and obtain results that were comparable to those provided by a professional unit administered by a trained observer.

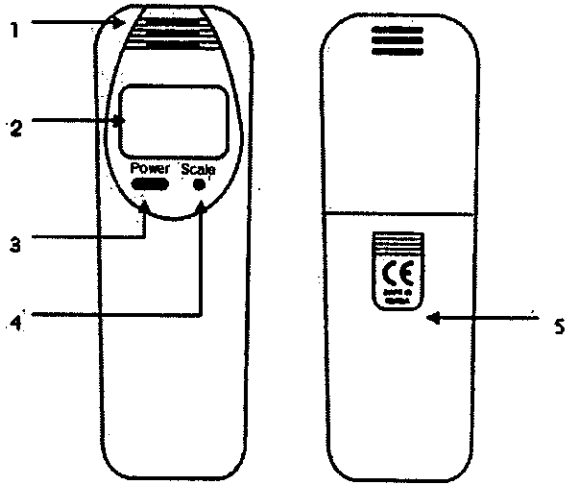
Instructions for Use

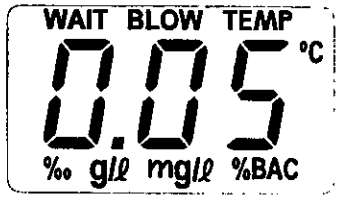
Model: PAD

The PAD Breath Alcohol Test System is a screening device for the rapid detection of alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication. The accuracy of this device has been established at a Blood Alcohol Concentrations of 0.008 and 0.032% BAC. Accuracy at a Blood Alcohol Concentration greater than 0.032% has not been established.

The Personal Alcohol Detector **PAD** analyzes a breath sample to detect alcohol in the lungs. This reading is then converted to blood alcohol concentration (BAC). This device is designed for over-the-counter use. No mouthpiece is required.

PART NAMES





1. Inhaler
2. Display window
3. Power
4. Scale
5. Battery Compartment Cover

CAUTION

PAD is a screening device. Each individual's body responds differently to alcohol. Driving skills may be impaired at a level below the legal blood alcohol limit. Do not rely on results to determine level of intoxication or ability to safely operate a

vehicle or machinery.

In addition, since this device visually shows the result on the Display Window, it is not appropriate for visually impaired people.

1. Operation

Make sure that you wait at least 25 minutes after drinking alcohol, smoking, or eating before testing. Please followed test procedure step 1~step3.

Step1.	**Power On/Off and Self test function.** Press Power button, and the device will start the **self-test function to check battery and sensor**. During the self-test function, Display Window will show the **count-down from '100' to '0'** with "WAIT" message. The self-test function typically lasts about 20 seconds. If it is normal at self-test function, the procedure will go to step 2. In the case of abnormal condition, the messages "L-b"(Low Battery) or "S-E"(Sensor damaged) will be display on the Display Window with a beep sound. And then, the device will turn off automatically.
Step2.	**Breath Sample** It is important that to blow properly to inhaler to test blood alcohol concentration (BAC). a. When you push power button, Display Window show number that how many you tested and then display "Wait" and countdown "100" to "0". b. When "0" and "BLOW" appear on the Display Window with a beep sound, blow your **deep breath** constantly into inhaler for 3-4 seconds. c. After you finished blow breath, the unit will beep again when display blood alcohol concentration.(BAC) d. If you don't blow within 20 seconds, the unit will turn off automatically with a beep sound.
Step3.	**Display** After the breath sample analyzed, the test result appears as percent measure of

	blood alcohol concentration (BAC) from 0.00% to 0.20 % on the Display Window. The BAC will be displayed for 20 seconds. And then, the device will turn off automatically.
Note:	If you want to repeat test, start again from Step 1 to Step 3.

2. Interpretation of the results

The generally accepted legal standard for alcohol intoxication in United States is 0.08 % BAC. However, your driving skills can be impaired even at a level of 0.03%BAC or lower. It is never safe to drink any amount of alcohol and drive. We recommend you "Don't drink and drive".

Test results	Interpretation
Less than 0.03 %BAC	Driving skills may be impaired even at low levels.
0.03 to 0.04 %BAC	Driving skills may be impaired at this level.
0.05 %BAC or Over	Driving skills are always impaired at this level.

- The result is displayed on the LCD screen by the increments of 0.01%BAC totally in 21 stages from 0.00%BAC to 0.20 %BAC. If alcohol concentration is above 0.20 %BAC, the message "HI" (high) will display.

3. Display window Messages

Display	Meaning	What do I have to do?
L - b (Low Battery)	Battery was discharged.	Replace with a new battery.
S- E (Sensor Error)	There is a problem with the sensor.	Contact Customer Service.
	The test environment is not good.	Test in a clean environment.

t - F (Test Fail)	Blowing strength or time is not enough.	Blow more strongly for 3~4 seconds.
L - t (Low Temperature)	Test temperature is under 10℃ (50℉)	Test at 10℃ (50℉) ~ 40℃ (104℉)
n - C (Need Calibration)	Test number is over 200 times.	Need Calibration at factory. Contact Customer Service.
HI (High Concentration)	Alcohol concentration is above 0.20%BAC.	Take sufficient rest.

4. Change Scale

Each countries use different scale. Please change scale when you go abroad.

Please follow the procedure for Change Scale.

Step 1	Please follow the test procedure step1, step 2.and step 3. When device display the test result, please push the **Scale** button. The scale % BAC will be change to ‰, **g/l,** and **mg/l** by push the Scale button.
Step 2	After select the Scale, please wait the device is turn off. From next time, device will show the scale what you choose.

5. Warnings.

a. Do NOT drop. This may damage the device, causing it not to work.

b. Do NOT tamper with the device. It may cause malfunction.

c. Please WAIT to test at least 25 minutes after drinking alcohol, smoking or eating. Otherwise, the remaining alcohol and smell in the mouth may lead to inaccuracy

d. Do not blow smoke, saliva, or other contaminants into inhaler, as the sensor may be damaged.

e. **Do not use it as a means to drink and drive.**

f. Do NOT keep the device in a dusty place. Dust accumulation on the PAD may cause

problems

g. Do NOT use or keep the device in a place where there are heavy moisture or traces of solvents such as Acetone. This may lead to malfunction.

h. Keep out of extreme temperature and out of reach of children.

i **YOU SHOULD HAVE YOUR PAD CALIBRATED EVERY 6 MONTHS OR AFTER 200 TESTS. FAILURE TO DO SO MAY CAUSE YOUR READINGS TO BE INACCURATE.** To obtain accuracy, the PAD requires recalibration every six months or after two hundred tests which comes first.

7. Specification

Sensor Type	Semiconductor Gas Sensor
Operating Range	0.00 %BAC to 0.20 %BAC
Warm-up Time	Less than 1 minute
Power Source	2 AAA Alkaline batteries (included)
Test Capacity	More than 150 measurements
Operating Temperature	Operating 10℃ (50℉) to 40℃ (104℉)
Display	3 digit LCD
Materials	ABS(body), PC(display part)
Dimensions	90 X 30 X 17 mm
Weight	45 g (including batteries)

8. Warranty

We warrant the product to be free from defects in workmanship or material for 12 months normal service from the date of purchase. Our duty under this warranty is limited to replacing, adjusting, or repairing the device if returned along with proof of purchase. This warranty is void if device has been tampered with or damaged by the user. Recalibration is a predict maintenance procedure required of any and all breathalyzers in order to maintain accuracy, and such, is not a warranty service.

9. Recalibration and Customer Service.

For recalibration or technical support, please contact us.

JC Global Inc.

23 Pepperidge Road

Paramus, NJ.07652

Toll Free : 888-401-5917 Contact Richard Lee.

Fax : 201-701-0337

Email : Sales@sejumicron.com Web: http//www.safe-drive.com

※This Instruction for use has been revised on 15 of Aug, 2011.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 21 2011

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C/O Business Association Co., Ltd
Certification Division
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Yuseong-Gu, Daejeon
Republic of Korea 305-500

Re: k110614
Trade Name: PAD (Personal Alcohol Detector)
Regulation Number: 21 CFR §862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class 1, reserved
Product Codes: DJZ
Dated: November 1, 2011
Received: November 17, 2011

Dear Ms. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if Known): K 110614

Device Name: PAD

Indications For Use:

The PAD Breath Alcohol Test System is a screening device for the rapid detection of alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcoholic intoxication.

	AND/OR	×
Prescription Use (Part 21 CFR 801 Subpart D)		Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices(OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K110614